



PREvention™ HLD
SOLUTION TEST STRIPS



INTENDED USE:

The Prevention™ HLD8 Solution Test Strip is a high level disinfectant concentration monitor dedicated for use with Prevention™ HLD8 High Level Disinfectant. The purpose of the Prevention™ HLD8 Solution Test Strip is to determine whether the concentration of hydrogen peroxide, the active ingredient in Prevention™ HLD8 High Level Disinfectant, is above the minimum recommended concentration (MRC) of 1.5%.

Prevention™ HLD8 Solution Test Strip for Prevention™ HLD8 High Level Disinfectant cannot be used to validate the disinfection process.

EXPLANATION OF THE TEST:

Prevention™ HLD8 Solution Test Strip is designed exclusively for monitoring the minimum recommended concentration (MRC) of Prevention™ HLD8 High Level Disinfectant. It is recommended that Prevention™ HLD8 High Level Disinfectant solution be tested before each usage in order to guard against dilution which may lower the hydrogen peroxide concentration of the solution below its MRC of 1.5% hydrogen peroxide.

NOTE: Not all disinfectant solutions are available in all areas.

CHEMICAL PRINCIPLE:

The Prevention™ HLD8 Solution Test Strip is based on a colorimetric sulfite-peroxide reaction, generating a blue/purple color. If sufficient hydrogen peroxide is present, initially after a test strip is immersed in the high level disinfectant solution for 2 seconds and removed, the solution will turn the original yellow color of the test strip to a uniform blue/purple and will maintain its blue/purple color at the 60 second (1 minute) read time. When the solution is at or below its MRC, the test strip will show non-uniform areas of blue/purple and pink colors at the 60 second read time.

REAGENTS:

The indicator pad at the end of the test strip is impregnated with sodium sulfite, dyes, and buffers.

STORAGE:

Store Prevention™ HLD8 Solution Test Strips in the original bottle with the cap tightly closed. Store at 6-30 °C (43-86°F) and 30-80% relative humidity (RH). Packaging contains an integral desiccant. Return unused strips to their bottle, and ensure lid is properly closed to prevent strip deterioration. Do not store in a freezer.

EXPIRATION:

The expiration date for the unopened bottle is printed on the bottle label. When opening the bottle for the first time, record the date opened in the space provided on the bottle label. The shelf life after the first opening of the bottle is 180 days, or the labeled expiration date, whichever is sooner. Do not use this product beyond the expiration date.

PRECAUTIONS:

- Do not use any strips 180 days after opening the bottle.
- Store between 6-30 °C (43-86 °F) and 30-80% RH.
- Protect strips from exposure to light, heat and moisture.
- Protect strips from exposure to oxidizing agents, strong acids/alkalis and detergents.
- Packaging contains an integral desiccant. Return unused strips to bottle, and ensure lid is properly closed to prevent strip deterioration.
- Use test strip immediately after removal from bottle.
- Only read the test strip result from the 'front' of the test strip, i.e. the side having text on the handle.

MATERIALS REQUIRED:

The following materials are not provided with the Prevention™ HLD8 Solution Test Strip but will be needed for the test:

- Watch or timer.
- Paper towel.
- Clean container (if required) to hold the Prevention™ HLD8 High Level Disinfectant.

SPECIMEN COLLECTION AND PREPARATION:

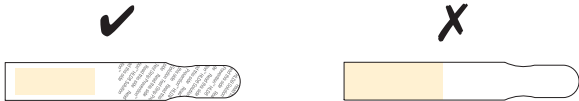
Prevention™ HLD8 Solution Test Strips can be used to test the high level disinfectant solution directly in the secondary solution container (i.e. soaking basin or automated endoscope reprocessor reservoir). When this is not feasible, remove approximately 30 ml of the high level disinfectant solution from the secondary container and place the solution into a clean container.

DIRECTIONS FOR USE:

1. Ensure that the high level disinfectant solution to be tested has been dispensed according to label instructions.
2. Ensure the test strips reach room temperature before testing.
3. Ensure that the high level disinfectant solution is 20°C (68°F) at a minimum.

CAUTION: THE TEST STRIP MAY NOT PERFORM PROPERLY IF USED WITH HLD SOLUTION BELOW 20 °C.

4. Remove a test strip from its bottle and close the bottle immediately. Hold the test strip such that the front side having the viewing 'window' for the indicator pad is facing you, as directed by the text on the handle.



5. Dip the indicator pad at the end of the test strip into the high level disinfectant solution for two (2) seconds and remove. Do not leave the test strip in the test high level disinfectant solution for longer than two seconds or "stir" the test strip in the high level disinfectant solution.

NOTE: Incorrect dipping technique, such as leaving the test strip in the high level disinfectant solution longer than the specified two seconds and/or swirling the test strip in the high level disinfectant solution, may wash off the reagents in the test strip pad. This can cause an incomplete color formation (FAIL) when testing a solution that will normally test as PASS.

6. Remove excess solution from the indicator pad by touching the short edge of the indicator pad to a paper towel. Do not shake the strip after removal. Immediately start a 60 second timer.

NOTE: When removing excess solution, incorrect technique, such as violently shaking the test strip and/or blotting the test strip with the pad face down against a paper towel, can remove the reagents and solution, which can again cause FAIL results for the high level disinfectant solutions that will normally test as PASS.

7. The yellow pad will become blue/purple. Continue to allow any indicator pad color to develop, and read the results of the color reaction present on the indicator pad in the viewing 'window' at 60 seconds.
 - a. If the pad is completely blue/purple, this indicates that the hydrogen peroxide concentration in the high level disinfectant solution being tested is above the MRC (PASS result).
 - b. If any pink appears on the indicator pad or the pad is not completely blue/purple, the hydrogen peroxide concentration of the high level disinfectant solution is at or below the MRC (FAIL result) and should be discarded.

CAUTION: If read in less than 60 seconds, the color change may be incomplete and may be interpreted incorrectly. Do not read the test strip after 60 seconds.

CAUTION: An indicator with a PASS result at 60 seconds could demonstrate a FAIL result beyond the 60 second read time.

8. Refer to the visual standard on the test strip bottle for interpretation of test results. See section Interpretation of Test Results for additional important information on the use of this product.

INTERPRETATION OF TEST RESULTS:

When reading the results of the test, the color of the Prevention™ HLD8 Solution Test Strips should be compared to the color chart provided on the test strip bottle. The entire indicator pad in the viewing window must be completely blue/purple at 60 seconds to achieve a PASS result, indicating that the concentration of hydrogen peroxide is above the MRC.

If any pink or other color appears on the indicator pad at 60 seconds, the test outcome is a FAIL result, verifying that the concentration of hydrogen peroxide in the high level disinfectant solution is at or below the MRC and the solution should be discarded.

During the reuse life of the high level disinfectant solution, the test must be performed according to these directions for use in order to determine the concentration of hydrogen peroxide in the high level disinfectant solution.

LIMITATIONS:

The Prevention™ HLD8 Solution Test Strip is to be used exclusively with Prevention™ HLD8 High Level Disinfectant.

QUALITY CONTROL (QC) PROCEDURES:

1. Testing Frequency

It is recommended that the testing of positive and negative controls be performed on one bottle of Prevention™ HLD8 Solution Test Strips for each lot received by the department. It is recommended that the testing of positive and negative controls be performed as new shipments of Prevention™ HLD8 Solution Test Strips are received.

2. Preparation of Control Test Solutions

To prepare positive and negative control test solutions for testing, obtain an unopened bottle of high level disinfectant. Verify that the labeled expiration date for the solution is within expiration.

- 2.1. The full strength solution is used as a Positive Control Test Solution.
- 2.2. To prepare a Negative Control Test Solution, dilute one part of full strength high level disinfectant with one part of water.
- 2.3. Label each control solution appropriately.

3. QC Testing Procedure

Test solutions must be 20°C (68°F) at a minimum.

CAUTION: THE TEST STRIP MAY NOT PERFORM PROPERLY IF USED WITH HLD SOLUTION BELOW 20 °C.

Following the DIRECTIONS FOR USE, individually test three test strips in each of the above freshly prepared solutions.

PASSING QC TEST:

The three test strips tested in the positive control test solution must show PASS results and the three test strips tested in the negative control test solution must exhibit FAIL results. Refer to the visual standard on the test strip bottle for interpretation of results.

FAILING QC TEST:

A failure to meet the positive control or negative control testing requirements demonstrates unsatisfactory QC test performance. This happens when one or more positive control test strips show FAIL results or one or more negative control test strips show PASS results. Refer to the visual standard on the test strip bottle for interpretation of results.

4. Failing QC Test Performance

If the QC test failed, contact Virox Technologies for advice. DO NOT USE. For technical product information, contact Virox Technologies at 1-800-387-7578.

PERFORMANCE CHARACTERISTICS:

The performance characteristics of Prevention™ HLD8 Solution Test Strips were established by testing the strips using Prevention™ HLD8 High Level Disinfectant with known concentrations of hydrogen peroxide under worst case conditions of germicide composition. The indicator exhibited no false positives in solutions containing 1.5% hydrogen peroxide when the testing was performed according to the Directions for Use. A false positive is a PASS result for a solution at or below 1.5% hydrogen peroxide.

WARNINGS & PRECAUTIONS:

- Discard used or expired strips in a trash receptacle in accordance with national, federal, state and local laws.
- Keep out of reach of children.
- Do not ingest the strip and/or expose to the eye.
- This device is single use. DO NOT REUSE TEST STRIPS.
- Test Strips such as Prevention™ HLD8 Solution Test Strips cannot be relied upon as a means of validating a disinfection process. Test Strips can only establish exposure to specific conditions within the specified performance limits established for the test strip.

WARNING: THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. Bottle should be closed immediately following removal of each test strip.

HOW SUPPLIED:

Product	Prevention™ HLD8 Solution Test Strips
Description	Chemical Indicators for monitoring of Prevention™ HLD8 High Level Disinfectant
Codes	AHPHLD8 (60 strips/bottle; 1 bottle per box)



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Manufactured in the UK